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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 08/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/814,161

Applicant(s)

GOH ET AL.

Examiner

Nelson Yang

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 34-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13, 34-54, 65 drawn to a sensing element for use in a light diffraction assay, classified in class 359, subclass 573.
  - II. Claims 14-33, drawn to a diffraction binding method for detecting at least two analytes in a medium simultaneously, classified in class 356, subclass 305.
  - III. Claims 55-64, drawn to a method of producing a sensing element for use in a light diffraction assay, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the sensing element of invention I can also be used as a specific binding adhesive.
3. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the sensing element of invention I can also be used as a specific binding adhesive.
4. Inventions II and III are unrelated, independent and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Invention II refers to a method for detecting at least two analytes in a medium simultaneously, requiring the step of illuminating a substrate and detecting the light diffracted from the substrate surface. Invention III refers to a method of producing a sensing element for use in a light diffraction assay requiring the step of depositing with a selected area on a surface of a substrate different distinct patterns of analyte-specific receptors.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for others, restriction for examination purposes as indicated is proper.

6. A request for an election by telephone was made to Ralph A. Dowell, who was unavailable at the time. However, during a telephone conversation with Lynn Schumacher on July 21, 2003, a provisional election was made without traverse to prosecute the invention of group II, claims 14-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13, 34-65 are withdrawn from further consideration by the examiner.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

### ***Claim Objections***

8. Claim 15 is objected to because of the following informalities: the limitation, "a part of each of said at least two patterns" is not written in a clear manner. It is not clear if the phrase as currently reads should be interpreted to mean that if there were multiple patterns on the substrate, illumination of part of only two of the patterns would be necessary, or if it should be interpreted as illumination of part of all the patterns on the substrate, of which there is at least two. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claim 20 recites the limitation "said light source" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no mention of a light source prior to this claim.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 14-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Yguerabide et al [US 6586193 B1].

Yguerabide anticipates the claims by teaching a diffraction binding assay method for detecting at least two analytes simultaneously in a medium. Yguerabide teaches a microarray or micropattern method of analysis using discreet spatially addressable areas of a solid-phase to detect different types of analytes. Each spatially addressable area or microspot may contain a different type of antibody, receptor, nucleic acid or the like. The arrangement of the spatially addressable areas on the solid-phase is dictated by the size of the solid-phase, the number of analytes or different areas that will be used, and the method of detection. Each of the spatially addressable microspots that contain a particular type of binding agent may be shaped as a square, circle, or any pattern depending on the methods used to make the microarray (column 94, lines 15-54, claim 1). The microarray is then exposed to different analyte samples to allow analytes to

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bind to the binding agents, and then illuminated. The pattern and amount of light scattering particles bound to different regions of an array or microarray is used to determine the level of gene expression, protein expression, identity of a nucleic acid sequence, identity of an organism or cell or specific strain thereof, and the pharmacological properties of a pharmaceutical agent (column 13, lines 17-27). Yguerabide also discloses that spherical particles of a certain size can also behave as diffraction gratings, which would be useful to detect more specifically and to greater sensitivity one or more analytes in many different types of samples (column 25, lines 23-35).

13. With respect to claim 15, Yguerabide teaches a method for detecting multiple analytes in a medium simultaneously involving the step of illuminating the substrate so that at least part of each pattern on the substrate is illuminated. Specifically, Yguerabide teaches the illumination of different populations, wherein each population specifically binds to a different predetermined analyte (claim 1, 70-73).

14. With respect to claim 16, Yguerabide teaches a method for detecting multiple analytes in a medium simultaneously that involves illuminating the patterns one at a time (column 98, lines 7-13, 29-35).

15. With respect to claim 17, the method Yguerabide teaches involves the detection of the formation of an image and the analysis of said image (column 13, lines 44-53, claims 51, 65, 72).

16. With respect to claims 18 and 19, Yguerabide teaches embodiments of the invention that include detecting light diffracted from the substrate prior to exposure of substrate to the medium for producing a baseline diffraction image and comparing it to the diffraction image representative of binding of one or more analyte-specific receptors (claims 1, 67).

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17. With respect to claims 20 and 21, the method Yguerabide teaches involves the use a monochromatic light or a laser as a light source (claim 13, claim 64). Yguerabide teaches that the light can be polychromatic or monochromatic, steady-state or pulsed, and coherent or not coherent light (column 10, lines 27-34). Yguerabide further discloses that the basic aspects of the invention apply as well to electromagnetic radiation of essentially all wavelengths, including ultraviolet, visible, near infrared, infrared, and microwave frequencies of electromagnetic radiation (column 26, lines 11-15).

18. With respect to claim 22-24, the method Yguerabide teaches involves the use of a substrate such as glass, which may be transparent, partially reflecting, or totally reflecting, depending on the angle for critical reflection (columns 66, 67). Furthermore, Yguerabide discloses embodiments of the invention that can be used in reflection contrast and differential interference contrast microscopy can be used with certain types of metal-like particles for measurement of multiple analytes on microarray chips and the like (column 97, lines 12-21). Yguerabide also discloses that light diffracted from the substrate is detected on the opposite side of the substrate (claim 54). Yguerabide further discloses that the detector can be located above or below the surface plane of the sample as well as on the same or opposite side of the sample plane where the illumination beam is located (column 59, lines 2-6, column 67, lines 33-41).

19. With respect to claim 25, Yguerabide also teaches the step of rinsing and drying the substrate prior to being illuminated (column 129, example 22).

20. With respect to claim 26, Yguerabide teaches an embodiment of the invention involving placement of the substrate in a cell (a prism arrangement) containing the medium being screened for analytes (column 66-67, claim 22).



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21. With respect to claim 27, the method Yguerabide teaches involves monitoring the intensities as a function of time (claims 67-73). Specifically, Yguerabide teaches the measurement of changes in scattered light as said particles or said multi-particle structures move in liquid phase.

22. With respect to claim 28, Yguerabide teaches an embodiment of the invention involving light illuminating the substrate to undergo total internal reflection from the substrate/medium interface (column 67, lines 33-41)

23. With respect to claim 29, Yguerabide teaches an embodiment of the invention that involves complementary strands of nucleic acids, proteins, carbohydrates, peptides, hormones, antibodies, viruses, antigenic substances, and bacteria (claim 38).

24. With respect to claim 30, Yguerabide teaches an embodiment of the invention that involves the use of a glass substrate (column 66, figure 11, column 110, lines 9-11).

25. With respect to claim 31 and 32, the method Yguerabide teaches involves contacting the substrate surface with a medium containing a standard material (a secondary binding pair member) that binds to the bound analytes (claim 36, 49). Yguerabide further discloses that the standard material can be antibodies (column 99, lines 17-27).

26. With respect to claim 33, the method Yguerabide teaches an embodiment of the invention involving the use of serum as a medium (column 123, example 10).

### ***Conclusion***

27. No claims are allowed.

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28. The following references are also cited as art of interest: Carter et al [US 4,608,344], Gustafson et al [5,478,527], Soini et al [6,204,068 B1] Susuki et al [6,215,549 B1], and Tsay et al [5,089,387].

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is 703-305-4508. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

NY  
July 31, 2003



LONG V. LE  
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08/01/03